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EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1633	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/511,515	BROWN, JASON PETER	
	Examiner	Art Unit	
	Q. JANICE LI, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 35* is/are pending in the application.

4a) Of the above claim(s) *6,9-17,24,30-33 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,18-23 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/04, 8/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I is acknowledged. The elected invention is drawn to a method for producing antibody using immortalized antibody-secreting cells, and species election drawn to a p53-/- null mouse expressing an oncogene myc under the control of the ecdysone-inducible promoter, wherein expression of myc promotes immortalization. The traversal appears to be directed to the species election on the ground(s) that the elected elements are simply illustrations of one embodiment and that other species could be combined to achieve the same outcome. The applicant asserts that a search of all claims can be made without serious burden. This is not found persuasive because it is maintained that each of the Inventions and species requires a separate search status and consideration. The inventions are mutually exclusive and independent methods using structural and functionally different materials for producing structurally different antibody-producing cells. For example, a search for p53-null mouse expressing the oncogene *myc* would not overlap with a search for a transgenic animal expressing a *bcl2* and *v-abl* oncogene. The different materials belong to different chemical entities and have distinct mode of operation. As such, the different species of group I requires different starting materials, reagents, steps, protocols, and technical considerations. Additionally, the applicant fails to submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case, and thus these

species are not obvious variants of each other based on the current record. The searches for different species of group I would have certain overlap, but they are not co-extensive. M.P.E.P. states, "FOR PURPOSES OF THE INITIAL REQUIREMENT, A SERIOUS BURDEN ON THE EXAMINER MAY BE PRIMA FACIE SHOWN IF THE EXAMINER SHOWS BY APPROPRIATE EXPLANATION OF SEPARATE CLASSIFICATION, OR SEPARATE STATUS IN THE ART, OR A DIFFERENT FIELD OF SEARCH AS DEFINED IN MPEP § 808.02". Therefore, it is maintained that these inventions are distinct due to their divergent subject matter. Further search of these inventions is not co-extensive, as indicated by the separate classifications and divergent search criteria. The requirement is still deemed proper and is therefore made **FINAL**.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 1-33, 35 are pending, however, claims 6, 9, 10-14, 15-17, 24, 30-33, 35 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1-5, 7, 8, 18-23, 25-29 are under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7, 8, 18-23, 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are vague and indefinite because of the claim recitation (1, 2), “capable of”, which describes an intrinsic property of the antibody-secreting cells, but the recitation does not require the cells express one or more transgenes. Hence, it is unclear whether it is a limitation.

Claim 21 recites the limitation "the antigen". There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 8, 18-23, 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention

is complete as evidenced by drawings, or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement;* Federal Register/ Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

At issue for written description in the instant case is the applicant fails to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed had possession of the claimed invention commensurate with the scope of the claims, specifically the starting material used for the claimed process, i.e. the genus of p53-/- double deletion mutant animals.

The claimed process requires "providing a transgenic animal having antibody-secreting cells", wherein the animal is a p53-/- null mutant (the elected species). Given the broadest reasonable interpretation, the claims embrace a genus of p53-/- animal, whose genome lacking the *p53* gene. In the specification, the applicant cites *Jacks et al.* (1994) for a p53 knockout mouse (Specification, page 22). The specification does not teach a genus of p53-null animals, nor such animals known to exist at the time before instant filing date. Accordingly, except for the p53 null mouse, the starting material essential for practicing the invention was not readily available to the public and the specification fails to provide adequate description commensurate with the scope of the

claims and the applicant fails to reasonably convey to the skilled in the art at the time of the filing, that the inventors were in possession of the claimed invention.

The Revised Interim Guidelines state "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (Column 3, page 71434), "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED WHERE AN INVENTION IS DESCRIBED SOLELY IN TERMS OF A METHOD OF ITS MAKING COUPLED WITH ITS FUNCTION AND THERE IS NO DESCRIBED OR ART-RECOGNIZED CORRELATION OR RELATIONSHIP BETWEEN THE STRUCTURE OF THE INVENTION AND ITS FUNCTION" (MPEP 2163 I-A). "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (Column 2, page 71436).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION *OF THE INVENTION*. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, *WHATEVER IS NOW CLAIMED.*" (See page 1117.) The specification does not "CLEARLY ALLOW PERSONS OF ORDINARY SKILL IN THE ART TO RECOGNIZE THAT [HE OR SHE] INVENTED WHAT IS CLAIMED." (See *Vas-Cath* at page 1116). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

In view of above considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention.

Claims 1-5, 7, 8, 18-23, 25-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing a p53-/- mouse, does not reasonably provide enablement for providing a genus of p53-/- animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the scope of the claims relative

to the state of the art and the levels of the skilled in the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

To the extent that the claimed methods are not adequately described in the instant disclosure, claims 1-5, 7, 8, 18-23, 25-29 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described, which is not conventional in the art.

Since the specification fails to provide the genus of the recited animals, the skilled in the art intending to make antibodies according to the claimed method have to first carrying out undue experimentation to make the required animals, which were known to be technically challenging, costly and time-consuming, particularly for animals other than the mouse.

Another concern for the claimed invention is whether the means of immortalization was suitable for the purpose of antibody production. The applicant teaches instant invention provides a method for immortalizing antibody-secreting cells via p53-/- mouse expressing an oncogene gene. Concerning the antibody-secreting cells of the p53-/- mouse expressing the *myc* gene (the elected species), *Yu* (Oncogene 2002;21:1922-7) teaches upon expression of the *myc*, the p53-/- mouse developed B-cell lymphoma, resembling human Burkitt lymphomas and mouse plasmocytomas (e.g.

the abstract). The ability of secreting antibody by such tumor cells was unknown, and not disclosed by the instant specification. To this end, *Benjamin et al*. (J Immunol 1982;129:1336-42) reports an investigation of the cellular origins of undifferentiated lymphomas of the Burkitt's and non-Burkitt's types, they examined immunoglobulin secretion by cell lines and biopsy samples from these tumors. Ig secretion by the tumor samples was found to be exclusively IgM. The secreted IgM was polymeric and associated with J chain, no other Ig classes were secreted (e.g. the abstract). *Marinkovic* (Int. J Cancer 2004;110:336-42) reports making B cell lines conditionally over-expressing *myc*, and several weeks into *in vitro* culture, all B-cell lines eventually lost expression of surface IgM (e.g. last paragraph, page 338), as such it is unpredictable whether conditional overexpressing the *myc* gene is a good choice for immortalizing B cells in the context of making antibodies. Moreover, *Marinkovic* also teaches *myc* activation has consistently shown in the art to induce genome instability and rapid accumulation of chromosomal abnormalities (e.g. page 340). Again, as such it is unpredictable whether conditional overexpressing myc is a good choice for immortalizing B cells in the context of making antibodies because the antibody secretion may have been different at the end of culture from what they were at the beginning due to the genome instability.

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

The following art rejections applied even though the Examiner is aware of the contradiction in the sections of enablement rejection and art rejection, and in view of the Office policy for compact prosecution, all issues relevant will put forward in the first action on merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, 8, 18-21, 23, 25-27, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Zaccolo et al*. (Int J Clin Res 1993;23:192-8), in view of *Weissinger et al*. (PNAS 1991;88:8735-9, IDS), *Yu et al*. (Oncogene 2002 Mar;21:1922-7) and *Felsher et al.* (Mol Cell 1999;4:199-207).

Claims are directed to a method for producing immortalized antibody-secreting cells via reversible expression of one or more transgene(s), wherein the antibody-secreting cells are obtained from a transgenic animal, and the methods further directed to using the immortalized cells for producing antibodies.

Zaccolo reviews the state of the art with respect to methods of producing antibodies using immortalized cell lines with a focus on improving methodologies for producing immortalized cell lines, humanize antibodies, and obviating the *in vivo* immunization steps, etc. (e.g. the abstract). In the review, two methods of making

immortalized antibody-secreting cells were mentioned, i.e. fusion of immune spleen lymphocytes with a suitable non-secreting myeloma partner, and immortalizing cells by EB virus infection (see e.g. column 1, page 193). *Zaccolo* teaches advantages and disadvantages of each technique (such as instability and low level of Ig production), and implicitly pointed to the need to further improve the immortalization process. *Zaccolo* does not teach using transgenic animals or oncogenes for preparing immortalized antibody-secreting cells.

Weissinger supplemented *Zaccolo* by establishing further development in the pertinent art using oncogene expression for direct immortalization of antibody-secreting B lymphocytes. *Weissinger* infected immunized mouse with a replication-defective retrovirus co-expressing oncogene v-*abl* and c-*myc*, and reports the virus rapidly induced plasmacytomas (tumors of antibody-secreting cells) in 100% of adult balb/c mice. *Weissinger* also reports the concentration, specificity and affinity of the antibodies produced by the plasmacytomas were comparable to monoclonal antibodies obtained with conventional hybridoma technology, and secreted IgG, IgM, and IgA antibodies (e.g. the abstract). *Weissinger* concluded "TO DATE, ALL ABL-MYC-INDUCED PLASMACYTOMAS HAVE BEEN VERY STABLE *IN VIVO* AND *IN VITRO*" and "THE USE OF THIS VIRUS MAY PROVE TO BE A VALUABLE ALTERNATIVE TO THE CONVENTIONAL HYBRIDOMA TECHNIQUE FOR PRODUCTION OF MONOCLONAL ANTIBODIES" (the paragraph bridging columns 1 & 2, page 8739).

Yu supplemented *Zaccolo* in view of *Weissinger* by establishing it was well known in the art using a transgenic mouse for directly immortalizing B lymphocytes. *Yu* reports obtaining bone marrow progenitor cells from p53 null mouse and transfecting

the cells with the *myc* gene. *Yu* concluded "INACTIVATION OF P53 AND OVEREXPRESSION OF MYC IS ALL THAT IS NECESSARY FOR THE DEVELOPMENT OF FULL-FLEDGED B-LYMPHOMAS" (=plasmacytomas in the mouse). *Yu* does not use a conditional/reversible immortalization regimen.

Felsher supplemented the deficiency by establishing using an inducible expression system controlling the expression of the *myc* gene for reversible tumorigenesis was known in the art. *Felsher* applied a tetracycline regulatory system to generate transgenic mice that conditionally express the *myc* oncogene in hematopoietic cells, wherein the oncogene could be turned on and off in the presence or absence of a chemical stimulus (tet).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by *Zaccolo* in view of *Weissinger* for preparing immortalized antibody-secreting cells using the method as taught by *Yu* and *Felsher* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the need for improved methods of immortalization as taught by *Zaccolo* in view of *Weissinger*. Given all the recited elements were known in the art for making instantly claimed transgenic mouse and antibody-secreting cells, "THE COMBINATION OF FAMILIAR ELEMENTS ACCORDING TO KNOWN METHODS IS LIKELY TO BE OBVIOUS WHEN IT DOES NO MORE THAN YIELD PREDICTABLE RESULTS." *KSR,* 127 S. Ct. at 1740, 82 USPQ2d at 1395-96. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Zaccolo et al*. (Int J Clin Res 1993;23:192-8), in view of *Weissinger et al*. (PNAS 1991;88:8735-9, IDS), *Yu et al*. (Oncogene 2002 Mar;21:1922-7), and *Felsher et al.* (Mol Cell 1999;4:199-207) as applied to claims 1-5, 7, 8, 18-21, 23, 25-27, 29 above, further in view of *Irsch et al*. (Immunotechnol 1995;1:115-25).

The details of the teaching of *Zaccolo* in view of *Weissinger, Yu, and Felsher* were detailed *supra*, which does not mention selecting an immortalized antibody-secreting cell via fluorescence activated cell sorting.

Irsch supplemented the deficiency by establishing the technique was well known in the art to the skilled for the purpose of selecting desired immortalized cells (e.g. the abstract, § 2.3 & 2.5).

Accordingly, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Zaccolo et al*. (Int J Clin Res 1993;23:192-8), in view of *Weissinger et al*. (PNAS 1991;88:8735-9, IDS), *Yu et al*. (Oncogene 2002 Mar;21:1922-7), and *Felsher et al.* (Mol Cell 1999;4:199-207) as applied to claims 1-5, 7, 8, 18-21, 23, 25-27, 29 above, further in view of *No et al*. (PNAS 1996;93:3346-51).

The details of the teaching of *Zaccolo* in view of *Weissinger, Yu, and Felsher* were detailed *supra*, which uses a tetracycline-inducible gene expression regulatory system, not the ecdysone-inducible gene expression system.

No supplemented the deficiency by establishing the technique was well known in the art to the skilled for the purpose of controlling gene expression in mammalian cells and transgenic mice.

Accordingly, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Zaccolo et al*. (Int J Clin Res 1993;23:192-8), in view of *Weissinger et al*. (PNAS 1991;88:8735-9, IDS), *Yu et al*. (Oncogene 2002 Mar;21:1922-7), and *Felsher et al.* (Mol Cell 1999;4:199-207) as applied to claims 1-5, 7, 8, 18-21, 23, 25-27, 29 above, further in view of *Yokoyama* (Curr Protoc Immunol 2001;Appendix 3G).

The details of the teaching of *Zaccolo* in view of *Weissinger, Yu, and Felsher* were detailed *supra*, which did not mention the method of storing cells.

Yokoyama supplemented the deficiency by establishing the technique was well known in the art to the skilled for the preserving cells and hybridoma (=immortalized B cells).

Accordingly, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7:30 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633

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Primary Examiner
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QL
March 9, 2009